



# UNITED STATES PATENT AND TRADEMARK OFFICE

W  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO.              | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|----------------------|---------------------|------------------|
| 10/069,305                   | 06/06/2002  | Gene H MacDonald     | 5470.276            | 1963             |
| 20792                        | 7590        | 06/12/2007           | EXAMINER            |                  |
| MYERS BIGEL SIBLEY & SAJOVEC |             |                      | ANGELL, JON E       |                  |
| PO BOX 37428                 |             |                      | ART UNIT            | PAPER NUMBER     |
| RALEIGH, NC 27627            |             |                      | 1635                |                  |
| MAIL DATE                    |             | DELIVERY MODE        |                     |                  |
| 06/12/2007                   |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/069,305             | MACDONALD ET AL.    |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | J. Eric Angell         | 1635                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 March 2007.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 27-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 27-32 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 22 February 2002 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

This Action is in response to the communication filed on 3/30/2007.

The amendment filed 3/30/2007 is acknowledged and has been entered.

Claims 27-32 are currently pending in the application and are addressed herein.

### ***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,789,245 (Dubensky et al., previously of record) in view of Chanas et al. (J. Gen. Virol., cited by Applicants in the IDS 11/12/2002).

Dubensky teaches an alphavirus vector (including a Sindbis virus) which encodes and expresses a heterologous nucleic acid sequence as well as methods of using said vector for prophylactic and/or therapeutic purposes. For instance, Dubensky teaches administering the alphavirus vector which expresses a therapeutic protein to an human for prophylactic and/or

therapeutic treatment of disease (e.g., see column 2, lines 57-67; column 3, lines 53-67; column 4, lines 1-41; column 7, lines 60-67; column 8, lines 1-6 and 41-67; etc.).

Dubensky does not teach to administer an antibody that specifically binds to the E1 glycoprotein of the alphavirus along with the alphavirus.

Chanas teaches that monoclonal antibodies specific for the E1 glycoprotein of Sindbis virus can, at particular concentrations (subneutralizing dilutions) enhance infectivity for macrophage-like cells (e.g., page 7: summary and introduction. Chanas demonstrates this effect by administering a sindbis virus (which is an alphavirus) with the E1 glycoprotein-specific antibodies to a mouse (e.g., see pages 43-44).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Dubensky and Chanas to create a method of using E1 glycoprotein specific antibodies with an alphavirus that comprises a heterologous sequence in order enhance the infectivity of the alphavirus in a subject, including a human to with a reasonable expectation of success.

The motivation to combine the references to create claimed invention and is provided by Chanas who teaches that subneutralizing dilutions of E1-glycoprotein antibodies enhance the infectivity of an alphavirus. Furthermore, the fact that the antibodies enhanced infectivity of the sindbis virus in mice demonstrates a reasonable expectation of success that infectivity of the alphavirus taught by Dubensky could be enhanced in a subject, including a human, without causing significant pathology.

4. Applicant's arguments, filed 3/30/2007, with respect to the rejection of claims under 35 U.S.C. 103(a) have been fully considered and, in view of the amendment, are persuasive. Therefore, the rejection has been withdrawn. However, upon consideration of the newly amended claims, a new ground(s) of rejection is made for the reasons set forth herein. The new grounds of rejection is necessitated by the amendment to the claims.

***Conclusion***

5. No claim is allowed.
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

Art Unit: 1635

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/  
Primary Examiner  
Art Unit 1635